DETAILED ACTION

The response filed January 28, 2008 presents remarks and arguments submitted to the office action mailed July 26, 2007 is herein acknowledged.

Applicant's arguments over the 35 U.S.C. 112 second rejection of claim 2 is persuasive due to the cancellation of the claims. Therefore, the rejection is herewith withdrawn.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 1-7, 10-12, 14-17 over Gervais (Pat. No. 6,340,695 - IDS) in view of Apfel (PONV Research – reference provided) is persuasive due to amendments made to the claims. Therefore, the rejection is herewith withdrawn.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of claims 8, and 9 over Gervais (Pat. No. 6,340,695 - IDS) in view of Apfel (PONV Research – reference provided) and Ansel et al.) is persuasive due to amendments made to the claims. Therefore, the rejection is herewith withdrawn.

Applicant's arguments over the Obvious Double Patenting rejection over U.S. Patent No. 6,340,695 is not fully persuasive. Therefore, the rejection is herewith modified to incorporate added limitations.

Claims 1, 5, 9, 11-12, 14-16, and 25 are pending.

Upon further consideration of the amended claims, the following rejections are made:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5, 9, 11-12, 14-16, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gervais (Pat. No. 6,340,695 - IDS) in view of Ansel et al. (previously presented) and Apfel et al. (A Simplified Risk Score for Predicting Postoperative Nausea and Vomiting. Anesthiology. 1999;91,693-700 – reference provided).

Gervais teaches a rapid onset formulation comprising pyridoxine HCl and doxylamine succinate useful in the treatment of nausea and vomiting comprising admistration of a therapeutically effective amount of the composition (see, column 1 lines 5-11, column 11 lines 1-3, and specifically claim 27). The preferred formulation of the Gervais' invention is in the form of an oral dosage form such as a tablet, pill or encapsulated beads or solution (column 2, lines 61-64). Further, the art teaches in the "most preferred embodiment, the formulation contains a core coated with an aqueous enteric coating. The core comprises the active ingredients pyridoxine HCl and doxylamine succinate (column 3, lines 39-42). Additionally, the reference teaches in

Example 1 a formulation wherein pyridoxine HCl and doxylamine succinate each weigh 10 mg/ tab, as recited in claim 11. The treatment of nausea and vomiting is especially, but not limited to, during pregnancy (column 1 lines 5-11), meeting the limitation of claim 14.

Ansel et al. is solely used to show that delayed release products usually are enteric-coated tablets or capsules designed to pass through the stomach unaltered, later to release their medication within the intestinal tract (page 229, column 1, first paragraph).

The reference does not specifically teach "reducing post-surgical vomiting" or "treating post-surgical vomiting" comprising the administration on an evening prior to, during, after (at regular intervals), continuously, on an outpatient bases, and a morning of the day of, as recited in claims 1, 5, 15-16 and 25.

However, the reference teaches the formulation of Doxylamine succinate and pyridoxine hydrochloride are used in the human and veterinary fields of medicine whenever symptoms of nausea and/or vomiting require medical intervention (column 2, lines 56-59)."

Anpfel et al. is used to show that PONV (postoperative nausea and vomiting) has been known in the prior art to be associated with general anesthesia. Anpfel further teaches a prophylactic antiemetic strategy should be considered when a patient is known to be at risk of PONV.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Doxylamine succinate and pyridoxine HCl formulation to

reduce post-surgical vomiting on an evening prior to, during, after (at regular intervals), continuously, on an outpatient bases, and a morning of the day of surgery in patients undergoing general anesthesia because the reference teaches the treatment of vomiting and nausea in general and Anpfel et al. teaches a prophylactic antiemetic strategy should be considered when a patient is known to be at risk of PONV. The motivation to administer the said formulation is because the prior art teaches the ingredients in treating nausea and vomiting (see claim 25, column 10, lines 62-64, and column 2, lines 56-61) and Anpfel et al. teaches general anesthetics associated PONV "increases patients' discomfort and also increase costs and unwarranted side effects (p 693 col 2)." Therefore, a skilled artisan would have reasonable expectation of treating post operative nausea and vomiting because Gervais teaches that the said formulation can be administered whenever symptoms of vomiting and nausea require medical intervention and Anpfel teaches a prophylactic antiemetic strategy in a patient at risk of PONV (postoperative nausea and vomiting).

In reference to Claim 12, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the dose range of Gervais compound by routine experimentation (see 2144.05 11). The motivation to optimize the dose range of the Gervais' final formulation is because one would have had a reasonable expectation of success in achieving the safest clinical outcome.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5, 9, 11-12, 14-16, and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-29, and 30 of U.S. Patent No. 6340695) in view of Ansel et al. (previously presented) and Apfel et al. (A Simplified Risk Score for Predicting Postoperative Nausea and Vomiting. Anesthiology. 1999;91,693-700 – reference provided).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the co-pending application recites a method of treating nausea and vomiting comprising administering a therapeutically effective amount of an enterically-coated pyridoxine HCl and doxylamine succinate rapid onset formulation, whereas the instant claims are to method of reducing post-surgical vomiting comprising administering to a patient undergoing general anesthesia a therapeutically effective amount of pyridoxine HCl and doxylamine succinate. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the

Doxylamine succinate and pyridoxine HCl formulation to reduce post-surgical vomiting on an evening prior to, during, after (at regular intervals), on an outpatient bases, and a morning of the day of surgery in patients undergoing general anesthesia because the reference teaches the treatment of vomiting and nausea in general and Anpfel et al. teaches a prophylactic antiemetic strategy should be considered when a patient is known to be at risk of PONV. The motivation to administer the said formulation is because the prior art teaches the ingredients in treating nausea and vomiting (see claim 25, column 10, lines 62-64, and column 2, lines 56-61) and Anpfel et al. teaches general anesthetics associated PONV "increases patients' discomfort and also increase costs and unwarranted side effects (p 693 col 2)." Therefore, a skilled artisan would have reasonable expectation of treating post operative nausea and vomiting because Gervais teaches that the said formulation can be administered whenever symptoms of vomiting and nausea require medical intervention and Anpfel teaches a prophylactic antiemetic strategy in a patient at risk of PONV (postoperative nausea and vomiting).

Response to Arguments

Applicant's arguments filed January 28, 2008 has been fully considered but they are not persuasive.

Applicant argues the state of the art at the time the application was filed did not contemplate its use for reducing the occurrence of post operative vomiting. More specifically, Gervais' formulation comprises Doxylamine succinate and pyridoxine hydrochloride is used after some nausea and/or vomiting symptoms are present and

requires intervention. Examiner states that Gervais teaches that the said formulation can be administered whenever symptoms of vomiting and nausea require medical intervention and Anpfel teaches a prophylactic antiemetic strategy in a patient at risk of PONV (postoperative nausea and vomiting). Hence, it would be obvious to one of ordinary skill in the art at the time the invention was made to use the Doxylamine succinate and pyridoxine HCl formulation to reduce post-surgical vomiting on an evening prior to, during, after (at regular intervals), on an outpatient bases, and a morning of the day of surgery in patients undergoing general anesthesia.

Applicant argues Apfel does not teach orally administering a first delayed release formulation and orally a second delayed release formulation comprising Doxylamine succinate and pyridoxine hydrochloride 0-6 hours after surgery. Further, that the common practice in antiemetic strategy is intravenous injections by a qualified professional. Examiner points to the teaching of the primary reference in which pyridoxine HCl and doxylamine succinate are useful in the treatment of nausea and vomiting comprising administration of a therapeutically effective amount of the composition (see, column 1 lines 5-11, column 11 lines 1-3, and specifically claim 27). The preferred formulation of the Gervais' invention is in the form of an oral dosage form such as a tablet, pill or encapsulated beads or solution (column 2, lines 61-64). Further, the art teaches in the "most preferred embodiment, the formulation contains a core coated with an aqueous enteric coating. The core comprises the active ingredients pyridoxine HCl and doxylamine succinate (column 3, lines 39-42). Ansel et al. is solely used to show that delayed release products usually are enteric-coated tablets or

capsules designed to pass through the stomach unaltered, later to release their medication within the intestinal tract (page 229, column 1, first paragraph). Applicant's arguments are not persuasive.

Applicant's argument over Ansel et al. (previously presented) rejection depends on the validity of the previous arguments which were not found persuasive.

Applicant's arguments with respect to the ODP have been considered but are moot in view of the modified rejections.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-

5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SREENI PADMANABHAN/

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